Guidance for FDA and Tobacco Retailers

Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers

(Revised) *

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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*** This is a revision to the second edition of this guidance, which issued in July 2012. Revisions are noted by date at the end of the guidance.**

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Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call 1-877-CTP-1373 listed on the title page of this guidance.

I. Introduction

This guidance document is intended to describe FDA's current policies with respect to civil money penalties and no-tobacco-sale orders for retailers who violate Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. 301 et seq.) requirements relating to tobacco products, including the requirement that tobacco products may not be sold or distributed in violation of FDA's "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." (75 FR 13225, codified at 21 C.F.R. Part 1140). With the finalization of this guidance document, several provisions in the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA") (Public Law 111-31) that relate to civil money penalties and no-tobacco-sale orders are effective. Section 103(q)(3) of the TCA.

The guidance document discusses:

- Definitions

[1] This guidance has been prepared by the Center for Tobacco Products at the U.S. Food and Drug Administration.

- How does FDA intend to identify violations of the FDCA relating to tobacco products?
- Does good-faith reliance on the presentation of a false government-issued ID constitute a violation of minimum-age requirements for the sale of tobacco products?
- When may FDA decide to seek civil money penalties and/or no-tobacco-sale orders?
- Procedures that apply if FDA seeks civil money penalties and/or no-tobacco-sale orders
- What amount of civil money penalty may be assessed for a violation of the FDCA relating to tobacco products (including a violation of regulations issued under Section 906(d) of the FDCA)?
- What factors must FDA consider when seeking a no-tobacco-sale order, and how long may such an order run?

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

On June 22, 2009, President Obama signed the Tobacco Control Act into law. The Tobacco Control Act amended the FDCA to give FDA important new authority to regulate the manufacture, marketing and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Civil Money Penalties. The Tobacco Control Act provides for civil money penalties for violations of FDCA requirements that relate to tobacco products. Section 303(f)(9) of the FDCA. Of special importance to retailers, these violations include the sale or distribution of tobacco products in a manner that violates regulations issued under Section 906(d) of the FDCA, such as FDA's "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents."[2]

The TCA provides that civil money penalties may not exceed certain limits, and requires a number of factors to be considered in determining the amount of a penalty under those limits.

Statutory limits vary according to the requirements that are violated, the number of violations, and other factors.

[2] Section 102(a)(1)(A) of the TCA provides that these regulations are deemed issued under Chapter IX of the FDCA. Section 906(d) of the FDCA provides the authority in Chapter IX for regulations restricting the sale or distribution of tobacco products, and FDA accordingly understands this regulation to have been issued under Section 906(d) of the FDCA.

For more information about the regulations, please see "Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents," available at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252758.htm.

- Maximum penalties for violating regulations issued under Section 906(d) of the FDCA, including the "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," are set forth at Section 103(q)(2) of the TCA. The penalties authorized for such violations range from a warning letter (for a first violation by a retailer with an approved training program) to a civil money penalty not to exceed $11,000 (for a sixth or each subsequent violation at the same retail location within a 48-month period). [3] *Id.*

- In general, penalties for violating other FDCA requirements relating to tobacco products may not exceed $15,000 for each violation or $1,050,000 for all violations adjudicated in a single proceeding. [4] Section 303(f)(9)(A) of the FDCA. Violations of certain provisions may be subject to enhanced penalties. Section 303(f)(9)(B) of the FDCA.

In determining the amount of civil money penalty under the relevant statutory limits, the following factors must be considered: the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. Section 303(f)(5)(B) of the FDCA.

No-Tobacco-Sale Orders. The Tobacco Control Act also adds Section 303(f)(8) to the FDCA, authorizing FDA to impose a no-tobacco-sale order against a person found to have committed repeated violations of restrictions promulgated under Section 906(d) of the FDCA at a particular retail outlet. "Repeated violations" is defined to mean at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation. Section 103(q)(1)(A) of the TCA.

In determining the duration of a no-tobacco-sale order, the same factors listed above for civil money penalties must be considered, and also whether employers have taken certain steps to promote compliance with the FDCA. Section 303(f)(5)(B) of the FDCA, Section 103(q)(1)(G) of the TCA.

Special Considerations and Mitigating Penalties. Section 103(q)(1)(F) of the TCA explains that good-faith reliance on a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products, provided that an employer takes effective steps to prevent such violations. Also relevant are Section 103(q)(1)(G) of the TCA and Section 303(f)(5)(B) of the FDCA, which are discussed above. Additionally, if a retailer has violated a restriction promulgated under section 906(d), the amount of any penalties that the retailer has paid to a State for the same violation will be considered for purposes of mitigating the civil penalty. Section 103(q)(2)(C) of the TCA.

[3] The Civil Money Penalty amounts listed here have been updated to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act.
[4] The Civil Money Penalty amounts listed here have been updated to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act.

Procedures. FDA must provide for timely and effective notice of each alleged violation at a particular retail outlet before conducting a follow-up compliance check at that outlet, and must provide notice of all previous violations at a particular outlet before a person can be charged with a violation at that outlet. Section 103(q)(1)(B) & (D) of the TCA. Civil money penalties and no-tobacco-sale orders may only be imposed after an opportunity for a hearing pursuant to the procedures established through regulations of the FDA for assessing civil money penalties (which are currently codified at 21 C.F.R. Part 17). Section 103(q)(1)(C) of the TCA, Section 303(5)(A) of the FDCA. At a retailer's request, such a hearing may be conducted by telephone or at the nearest FDA regional or field office (or, if a no-tobacco-sale order is at issue, at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available). Section 303(f)(8) of the FDCA, Section 103(q)(1)(C) of the TCA. A procedure for expedited administrative appeal of an alleged violation must also be provided. Section 103(q)(1)(C) of the TCA.

Effective Date. Section 103(q)(3) of the TCA provides that several provisions that relate to civil money penalties and no-tobacco-sale orders will take effect upon issuance of the guidance described in Section 103(q)(1) of the TCA. With issuance of this final guidance, the conditions in Section 103(q)(3) of the TCA are satisfied and the provisions it identifies are effective.

III. Discussion

A. Definitions

FDA intends to use the following definitions in implementing no-tobacco-sale order provisions and civil money penalty provisions relating to tobacco products.

1. **Civil money penalty**: The term "civil money penalty" means a fine assessed under Section 303(f)(9) of the FDCA for violations of the FDCA.

2. **No-tobacco-sale order**: The term "no-tobacco-sale order" refers to an order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of time under Section 303(f)(8) of the FDCA. Violations of such an order are punishable as violations of the FDCA. Section 301(oo) of the FDCA.

3. **Person**: The term "person" is not limited to a natural person, but includes individual, partnership, corporation, and association. Section 201(e) of the FDCA.

4. **Retailer**: The term "retailer" means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted. Section 900(14) of the FDCA.

5. **Repeated violation**: For purposes of Section 303(f)(8) of the FDCA, which relates to no-tobacco-sale orders, the TCA defines the term "repeated violation,"

to mean "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation…." Section 103(q)(1)(A) of the TCA. FDA understands this to mean that there is a "repeated violation" for purposes of Section 303(f)(8) if:

- There are at least five violations of requirements issued under Section 906(d) of the FDCA at a particular outlet;
- Each of the five violations represents the second or subsequent violation of a particular requirement; and
- Each of the five violations occurs within 36 months.

Thus, if there are six violations of 21 CFR 1140.14(b)(1) at the same outlet, and the last five of the violations take place at the outlet within 36 months, that would constitute a "repeated violation" for purposes of Section 303(f)(8) of the FDCA. Or, if there are four violations of 21 CFR 1140.14(b)(1), two violations of 21 C.F.R. 1140.14(c), and two violations of 21 CFR 1140.14(d) at a retail outlet, and the last three violations of 21 C.F.R. 1140.14(b)(1), and the second violation each of 21 C.F.R. 1140.14(c) and (d) take place within 36 months, that would constitute a "repeated violation" for purposes of Section 303(f)(8) of the FDCA. In each of these examples, the first violation of a requirement would not count toward the total, but each second or subsequent violation would. FDA also understands that each of the violations that counts toward the total must fall within a 36-month period, but that an initial violation (i.e., a first violation of a provision, which does not count toward the total of five required) may fall outside the 36-month period.

6. **Tobacco product**: The term "tobacco product" means "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." Section 201(rr) of the FDCA. This term does not include an article that is a drug, a device, or a combination product as defined in the act. Section 201(rr) of the FDCA. Thus, the term is not limited to products containing tobacco, but also includes components, parts, and accessories of tobacco products, whether they are sold for further manufacturing or for consumer use. For example, tobacco, papers, and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

B. How does FDA intend to identify violations of the FDCA relating to tobacco products?

FDA intends to conduct compliance check inspections to identify violations of FDCA requirements relating to tobacco products, including the sale or distribution of tobacco products in violation of the "Regulations Restricting the Sale and Distribution of

Cigarettes and Smokeless Tobacco To Protect Children and Adolescents." Such inspections may be conducted by FDA officers or employees, officers or employees of other federal departments or agencies, or certain state officers or employees commissioned by FDA. Section 702 of the FDCA.

C. Does good-faith reliance on the presentation of a false government-issued ID constitute a violation of minimum-age requirements for the sale of tobacco products?

With respect to minimum-age requirements for the sale of tobacco products, including regulations issued under section 906(d) of the FDCA, good faith reliance on the presentation of a false government issued photographic identification that contains a date of birth does not constitute a violation if the retailer has taken effective steps to prevent such violations, including -

- adopting and enforcing a written policy against sales to minors;
- informing its employees of all applicable laws;
- establishing disciplinary sanctions for employee noncompliance; and
- requiring its employees to verify age by way of photographic identification or electronic scanning device.

Section 103(q)(1)(F) of the TCA.

D. When may FDA decide to seek civil money penalties and/or no-tobacco-sale orders?

Although FDA is not required to issue a warning letter before taking further regulatory action, the first time FDA identifies violation(s) at a retail outlet, it generally intends to issue a Warning Letter that describes each violation.

Warning Letters will be sent by certified mail, registered mail, or personal delivery to: (1) the retailer, at the address the retailer specified when it registered with a State as a tobacco retailer, if the address is available to FDA and is not unreliable; or (2) the retailer's registered agent, if the retailer identified an agent to FDA prior to the violation and the address it provided for the agent is not unreliable. If FDA cannot reach the retailer or its agent through any of the methods described in the previous sentence, FDA intends to attempt to reach the retailer through other means, for example, the retailer at the address otherwise identified by the State or FDA.

FDA intends, in Warning Letters, to remind the retailer that failure to comply with the requirements of the FDCA relating to tobacco products may result in further FDA enforcement action, including civil money penalties, a no-tobacco-sale order, and/or injunction. FDA also intends that these letters will provide contact information and seek the retailer's response to the alleged violations.

After FDA has issued a Warning Letter with respect to a retail outlet, it intends to conduct a follow-up compliance check of that outlet. FDA intends to conduct follow-up compliance checks without further notice to the retailer or retail outlet.

If FDA identifies violation(s) at a retail outlet during a follow-up compliance check, or at a subsequent inspection at that retail outlet, it generally intends to seek civil money penalties to the extent they are appropriate. If there have been repeated violations at the outlet and a no-tobacco-sale order would be appropriate in light of the factors discussed below in Section G, FDA also generally intends to seek a no-tobacco-sale order.

E. Procedures that apply if FDA seeks civil money penalties and/or no-tobacco-sale orders

FDA will only charge a person with a violation at a particular retail outlet after providing notice to the retailer of all previous violations identified by FDA at that outlet. Section 103(q)(1)(D) of the TCA.

Civil money penalties and no-tobacco-sale orders are initiated by FDA filing a Complaint with the Division of Dockets Management of the agency and serving the Complaint upon the respondent (the tobacco retailer or other appropriate person). Upon being served, the respondent usually then has two options: (1) either pay the penalty sought in the Complaint or receive a copy of the no-tobacco-sale order and comply with its terms unless or until it is terminated (no contest); or (2) file an Answer with the Division of Dockets Management and contest some or all of the agency's allegations. 21 C.F.R. 17.9.

If a respondent chooses to contest the matter, it must file an Answer to the Complaint, pursuant to 21 C.F.R. 17.9, within 30 days of the date of service of the Complaint. The Answer must admit or deny each of the allegations made in the Complaint, and also include any and all defenses to the action and reasons or explanations why the penalty and assessment should be less than the amount requested by the Complaint. If the respondent timely files an Answer, it is entitled to a hearing according to the procedures established in FDA's regulations governing civil money penalty proceedings, codified in 21 C.F.R. Part 17.

After submitting an Answer, a respondent and its representatives may engage in settlement discussions with FDA regarding the civil money penalty and/or the no-tobacco-sale order. Respondents may present relevant mitigating factors or arguments for FDA to consider reducing the penalty amount or terms of the order. If FDA and the respondent arrive at an agreed settlement of a Complaint seeking a civil money penalty, respondent will pay that amount and the case is concluded. If FDA and the respondent arrive at an agreed settlement of a Complaint seeking a no-tobacco-sale order, respondent will receive a copy of the order and will be expected to comply with its terms unless or until it is terminated. Even if charges are resolved through a settlement agreement, any violations that occurred will be counted in determining the total number of violations for purposes of subsequent enforcement actions.

Cases that are not settled will be decided by an Administrative Law Judge (ALJ) in an administrative hearing. Under Section 103(q)(1)(C) of the TCA, at a retailer's request, a hearing can be held by telephone or at the nearest FDA regional or field office. For cases involving no-tobacco-sale orders, at retailer's request, a hearing can be held by telephone, at the nearest FDA regional or field office, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such facility is available. Upon request, for appropriate cause, the ALJ may expedite the schedule for various aspects of the hearing.

In advance of a hearing, parties are required to exchange exhibits and written direct testimony. 21 C.F.R. 17.25 and 17.37. Parties can choose to "rest" after this exchange, or request an opportunity to cross-examine the opposing party at an oral hearing and/or submit legal briefs. After resting, or after an oral hearing and/or further briefing, the ALJ will render an initial decision based on the evidence submitted. 21 C.F.R. 17.45.

After the ALJ renders an initial decision, either party can appeal to the Department of Health and Human Services (DHHS) Departmental Appeals Board (DAB), pursuant to 21 C.F.R. 17.47. The respondent may appeal a decision of the DAB to the U.S. Court of Appeals for the District of Columbia or any other circuit in which the respondent resides or transacts business. Section 303(f)(6) of the FDCA, 21 U.S.C. 333(f)(6).

F. What amount of civil money penalty may be assessed for a violation of the FDCA relating to tobacco products (including a violation of regulations issued under Section 906(d) of the FDCA)?

The TCA provides that civil money penalties may not exceed certain limits, and requires a number of factors to be considered in determining the penalty under those limits.

Statutory limits. Statutory limits vary according to the requirements that are violated, the number of violations, and other factors.

- *For violations of regulations issued under Section 906(d) of the FDCA*. The statute provides two schedules of maximum penalties for violations of such regulations -- one for retailers with an approved training program (Section 103(q)(2)(A)(i) of the TCA), and another for retailers that do not have an approved training program (Section 103(q)(2)(A)(ii) of the TCA).[5] FDA intends to promulgate regulations establishing standards for approved retailer training programs. Until it does, the agency intends to seek penalties within the range provided by Section 103(q)(2)(A)(i) of the TCA (for retailers with an approved

[5] For more information about the retailer training program, please see Guidance for Industry "Tobacco Retailer Training Programs," available at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm218898.htm.

training program), whether or not the retailer has implemented a training program. Those penalties shall not exceed: [6]

I. in the case of the first violation, $0.00 together with the issuance of a warning letter to the retailer;

II. in the case of a second violation within a 12-month period, $250;

III. in the case of a third violation within a 24-month period, $500;

IV. in the case of a fourth violation within a 24-month period, $2,000;

V. in the case of a fifth violation within a 36-month period, $5,000; and

VI. in the case of a sixth or subsequent violation within a 48-month period, $11,000 as determined by the Secretary on a case-by-case basis.

- *Violations of other FDCA requirements relating to tobacco products*. In general, penalties for violating other FDCA requirements relating to tobacco products may not exceed $15,000 for each violation or $1,050,000 for all violations adjudicated in a single proceeding. [7] Section 303(f)(9)(A) of the FDCA. Violations of certain FDCA provisions are subject to enhanced penalties. Section 303(f)(9)(B) of the FDCA.

Other factors that must be considered in determining the amount of civil money penalty. In determining the amount of civil money penalty, the following factors must be considered: the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. Section 303(f)(5)(B) of the FDCA.

If a retailer has violated a restriction promulgated under section 906(d), the amount of any penalties that the retailer has paid to a State for the same violation will be considered for purposes of mitigating the civil penalty. Section 102(q)(2)(C) of the TCA.

Finally, FDA may also take into account whether a retailer has implemented a training program in determining whether to seek less than the maximum allowed. Additional information about such programs may be found in FDA's Guidance for Industry, "Tobacco Retailer Training Programs." [8]

[6] The Civil Money Penalty amounts listed here have been updated to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act.
[7] The Civil Money Penalty amounts listed here have been updated to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act.
[8] For more information about the retailer training program, please see Guidance for Industry "Tobacco Retailer Training Programs," available at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm218898.htm.

G. What factors must FDA consider when seeking a no-tobacco-sale order, and how long may such an order run?

If there are repeated violations[9] of a restriction promulgated under Section 906(d) of the FDCA at a particular retail outlet, a no-tobacco-sale order may be imposed to prohibit the sale of tobacco products at that outlet. Section 303(f)(8) of the FDCA, Section 103(q)(1)(A) of the TCA.

As noted above, FDA generally does not intend to seek a no-tobacco-sale order the first time that an inspection identifies violations at a retail outlet, and instead intends to send a Warning Letter.

In determining whether a no-tobacco-sale order may be imposed, it is necessary to consider whether a retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including

- adopting and enforcing a written policy against sales to minors;
- informing its employees of all applicable laws;
- establishing disciplinary sanctions for employee noncompliance; and
- requiring its employees to verify age by way of photographic identification or electronic scanning device.

Section 103(q)(1)(G) of the TCA. If a no-tobacco -sale order is imposed, FDA will also consider these factors in deciding whether to compromise, modify, or terminate the order. *Id.*

In determining the period to be covered by a no-tobacco-sale order, the same factors that are relevant to determining the amount of a civil money penalty must be considered, that is: the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. Section 303(f)(5)(B) of the FDCA.

If a no-tobacco-sale order permanently prohibits an individual retail outlet from selling tobacco products, the order must include provisions that allow the outlet, after a specified period of time, to request that FDA compromise, modify, or terminate the order. *Id.*

Document History:

- March 2011 – First edition of guidance was issued.
- July 2012 – Footnote #2 was revised to change the first citation from Section 102(q)(1)(A) of the Tobacco Control Act to Section 102(a)(1)(A); the table of contents was reformatted.

[9] Defined to mean at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation - *see* Definitions above.

- June 2014 – Pages 3 and 9 were updated with new Civil Money Penalty amounts that reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act; footnotes 2 and 3 were updated with a new URL and edited to clarify that the guidance is now final; footnote 4 was edited to clarify that the guidance is now final.